REMARKS

Applicant respectfully requests favorable reconsideration of this application light of the following remarks.

By this Amendment, Applicant amends claims 40 and 41. The Amendment to claims 40 and 41 finds non-limiting support at least in Figs. 2 and 5; and pp. 3, 4, and 9 of the original application. No new matter has been added.

On page 3 of the Office Action, the drawings were objected to. In particular, the Office Action asserts that the feature of a "conical sealing portion having a diameter that continuously increases from the cylindrical portion to a position proximate the lid portion," in claim 40 "must be shown or the feature[] cancelled from the claim[]." See page 3 of the Office Action. Although Applicant does not necessarily agree with the drawing objection, in order to expedite prosecution in this case, Applicant has amended claim 40 to clarify that the "sealing portion ha[s] a first portion adjoining [a] cylindrical portion and a second portion extending from the first portion to a position proximate [a] lid portion, wherein the first portion is sloped from the cylindrical portion to the second portion so as to form an acute angle with respect to a longitudinal axis of the piercing mandrel." Applicant submits that at least Figs. 2 and 5 fully support this feature. Accordingly, Applicant respectfully request reconsideration and withdrawal of the drawing objection.

On page 5 of the Office Action, claims 40-52 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,211,638 to Dudar et al. (hereinafter "Dudar") in view of U.S. Patent No. 3,977,555 to Larson (hereinafter "Larson"), and further in view of Brony. Applicant respectfully traverses the rejections.

No combination of Dudar, Larson, and Brony discloses or suggests the present claims. For example, as-amended independent claim 40 recites a plastic fluid transfer device comprising, among other aspects,

> a piercing mandrel formed integrally with and extending from the lid portion, the piercing mandrel including a piercing portion configured to pierce completely through a thickness of the elastic stopper[,] ... the piercing portion including a pointed end and a cylindrical portion of constant diameter, the piercing mandrel further including a sealing portion having a first portion adjoining the cylindrical portion and a second portion extending from the first portion to a position proximate the lid portion, wherein the first portion is sloped from the cylindrical portion to the second portion so as to form an acute angle with respect to a longitudinal axis of the piercing mandrel, and wherein the first portion of the sealing portion is configured to be disposed between the external surface of the elastic stopper and the internal surface of the elastic stopper when the piercing mandrel pierces completely through the thickness of the elastic stopper, and the first portion of the sealing portion being configured to seal a tear in the thickness of the elastic stopper formed upon eccentric application of the fluid transfer device to the elastic stopper.

No combination of Dudar, Larson, and Brony disclose at least these aspects of the claims alone or in combination with other aspects of the claims.

Dudar discloses a vial adapter configured to be coupled to a standard vial. In one embodiment, Dudar teaches that vial adaptor 736 has a hole 750 centered in a top member 740, which is aligned with a fluid flow member 738. Dudar further teaches that an adapter spike 752 is contiguous with the hole and "has a generally cylindrical, hollow body portion 754 which tapers into a solid center point 756." See col. 12, lines 15-58 of Dudar. Dudar does not disclose or suggest that adapter spike 752 includes "a sealing portion having a first portion adjoining the cylindrical portion and a second portion extending from the first portion to a position proximate the lid portion, wherein the first

portion is sloped from the cylindrical portion to the second portion so as to form an acute angle with respect to a longitudinal axis of the piercing mandrel," as recited in as-amended claim 40. Indeed, the Office Action concedes that Dudar fails to "teach a conical sealing portion proximal of the piercing portion for sealing tears in the elastic stopper of the vial." See page 5 of the Office Action.

Larson teaches a unit dose vial 10 with a safety cap 22 having a cap portion 24 and a needle structure 34. The needle structure 34 includes "a generally cylindrical body 36 provided with a small diameter downwardly tapering lower end extension 38 which is sharpened at is lower end as at 40." See col. 3, lines 16-20 of Larson. As shown in Fig. 4, Larson discloses that needle structure 34 includes an enlargement 66 proximal lower end extension 38.

In formulating the rejection, the Office Action asserts that enlargement 66 corresponds to a sealing portion. See page 6 of the Office Action. Even assuming that is correct, which Applicant does not concede, as-amended claim 40 requires that the sealing portion "ha[s] a first portion adjoining the cylindrical portion and a second portion extending from the first portion to a position proximate the lid portion, wherein the first portion is sloped from the cylindrical portion to the second portion so as to form an acute angle with respect to a longitudinal axis of the piercing mandrel." As shown in Fig. 4, enlargement 66 is not sloped from lower extension 38 to inner end portion 44 so as to form an acute angle with respect to a longitudinal axis of the needle structure 38; instead enlargement 66 is rounded between lower extension 30 and inner end portion 44.

Additionally, claim 40 requires that "the first portion of the sealing portion is configured to be disposed between the external surface of the elastic stopper and the internal surface of the elastic stopper when the piercing mandrel pierces completely through the thickness of the elastic stopper, and the first portion of the sealing portion [is] configured to seal a tear in the thickness of the elastic stopper formed upon eccentric application of the fluid transfer device to the elastic stopper." Larson also fails to disclose or suggest this feature of claim 40.

In particular, Larson discloses that enlargement 66 abuts against seal 14 and depresses seal 14 when the bead is substantially received by cap portion 24. Col. 4, lines 41-43 of Larson. Larson does not teach that the bulbous enlargement 66 penetrates the thickness of the cap. Indeed, in contrast to the assertions on page 3 of the Office Action, Larson is at best silent with regard to penetration of the stopper.

Brony fails to cure the deficiencies of Larson. While Brony discloses a conical shaped syringe, Brony fails to disclose or suggest that the syringe is "configured to seal a tear in the thickness of [an] elastic stopper form upon eccentric application of the fluid transfer device to the elastic stopper," as required by claim 40.

Accordingly, for at least these reasons, independent claim 40 is allowable. Independent claim 41, although of different scope, recites similar features. Therefore, independent claim 41 is allowable for at least the same reasons discussed above. Applicant requests reconsideration and withdrawal of the Section 103(a) rejection of independent claims 40 and 41 based on Dudar, Larson, and Brony.

Applicant further submits that claims 42-52 depend either directly or indirectly from independent claim 40, and are therefore allowable for at least the same reasons

that independent claim 40 is allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the cited references, and therefore at least some also are separately patentable.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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